K111616

027

Saeshin Precision Co., Ltd.
#93-15, Paho-Dong, Dalseo-Gu, Daegu, 704-220, Republic of Korea
Tel 82 53-587-2345 Fax 82 53-587-2347

AUG 19 2011

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92(c).

Date: October 11, 2010

1. Company and Correspondent making the submission:

	Company
Name	Saeshin Precision Co., Ltd.
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Phone	+82 53-587-2345
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Contact	Y. S. Lee

2. Device:
   Proprietary Name – E-CUBE
   Common Name – Dental handpiece and accessories
   Classification Name – Handpiece, Direct drive, AC-powered

3. Predicate Device:
   X-Smart Easy, K092614
   STRONG Implant Handpiece, K092412

4. Classifications Names & Citations:
   EKX, 872.4200

5. Description:
   The E-CUBE is an AC-powered device that includes a hand-held motor and controller for regulation of speed and direction of rotation or a contra-angle attachment for dental implant surgery.

6. Indication for use:
   The E-CUBE is indicated for use by dentists in standard endodontic procedures using rotary endodontic files and rotary endodontic drills(Gates-Glidden).

7. Review:
   The E-CUBE has the same device characteristics as the predicate device, the X-Smart Easy; intended use, material, design and use concept are similar.

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The biocompatibility of the patient contact parts has been demonstrated through the cytotoxicity, sensitization and irritation testing by ISO 10993-1 Biological evaluation of medical devices – Part1 Evaluation and Testing. The contacting materials of the E-CUBE are the same as those of the STRONG Implant Handpieces (K092412).

The E-CUBE conforms to IEC 60601-1 Medical electric equipment, Part 1: General requirements for safety and IEC 60601-1-2 Medical electric equipment, General requirements for safety collateral standard electromagnetic compatibility.

Based on the comparison of intended use and technical features, the E-CUBE is substantially equivalent to the predicate device.

8. Conclusions:

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807, and based on the information provided in this premarket notification Saeshin Precision Co., Ltd. concludes that the E-CUBE are safe and effective and substantially equivalent to predicate devices as described herein.

9. Saeshin Precision Co., Ltd. will update and include in this summary any other information deemed reasonably necessary by the FDA.

END

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Saeshin Precision Company, Limited
C/O Mr. Marc M. Mouser
Responsible Third Party Official
Underwriters Laboratories, Incorporated
2600 North West Lake Road
Camas, Washington 98607

AUG 19 2011

Re: K111616
Trade/Device Name: E-Cube
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Headpiece and Accessories
Regulatory Class: I
Product Code: EKX
Dated: August 12, 2011
Received: August 15, 2011

Dear Mr. Mouser:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number K 111616

Device Name: E-CUBE

Indication for use:

The E-CUBE is indicated for use by dentists in standard endodontic procedures using rotary endodontic files and rotary endodontic drills(Gates-Glidden).

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21CFR801 Subpart D) (Per 21CFR807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K111616